



4-005-25 SD

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :
QUINN ET AL. : GROUP ART UNIT: 3305
SERIAL NO: 08/049,231 :
FILED: APRIL 19, 1993 : EXAMINER: NASSER
FOR: THERMODILUTION CATHETER :
HAVING A SAFE, FLEXIBLE
HEATING ELEMENT

37 CFR 1.67 SUPPLEMENTAL DECLARATION

HONORABLE COMMISSIONER OF PATENTS & TRADEMARKS
WASHINGTON, D.C. 20231

I. 37 CFR 1.67(a) - COMPLIANCE WITH 37 CFR 1.63

A. 37 CFR 1.63(a)

(1) 37 CFR 1.63(a)(1) - Accordance with 37 CFR 1.68

The undersigned is aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements made on knowledge of the undersigned are true and all statements made on information and belief of the undersigned are believed to be true. (See the signatures at the bottom of this declaration for completion of satisfaction of 37 CFR 1.63(a)(1).)

(2) 37 CFR 1.63(a)(2)

The specification is that of application serial No. 08/049,231.

(3) 37 CFR 1.63(a)(3)

The inventors are:

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(4) 37 CFR 1.63(a)(4)

The inventors are joint inventors of the invention that is defined by claims 63-80.

B. 37 CFR 1.63(b)

(1) 37 CFR 1.63(b)(1)

The undersigned have reviewed and understand the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

(2) 37 CFR 1.63(b)(2)

The undersigned believe the named inventors to be the original and first inventors of the subject matter which is claimed and for which a patent is sought.

(3) 37 CFR 1.63(b)(2)

The undersigned acknowledge the duty to disclose to the Patent Office all information known to be material to patentability.

C. 37 CFR 1.63(c) is not relevant.

D. 37 CFR 1.63(d) is not relevant.

II. 37 CFR 1.67(B) - REASON FOR THIS DECLARATION

A. 37 CFR 1.67(b)(1)

Claims 63-80 are presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented. These claims read as follows:

--67. A multi-lumen, multi-purpose cardiac catheter comprising:

(a) a multi-lumen main body portion;

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes, wherein:

(d) said multi-lumen main body portion comprises:

(i) at least one lumen for holding and supporting fiber optic filaments;

(ii) at least one lumen for receiving thermal element connectors;

(iii) at least one lumen for receiving a device for temperature measurement;

(iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and

(v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) an external thermal element is placed on said multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

(j) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

68. The multi-lumen, multi-purpose cardiac catheter of claim 67 wherein:

(a) said multi-lumen main body portion includes a necked-down portion;

(b) said necked-down portion is disposed near the distal end of said multi-lumen main body portion; and

(c) said external thermal element is disposed in said necked-down portion.

69. The multi-lumen, multi-purpose cardiac catheter of claim 68, wherein:

(a) said necked-down portion is 5-10 centimeters in length and

(b) said necked-down portion is disposed approximately 14-15 centimeters from the distal end of said multi-lumen main body portion.

70. The multi-lumen, multi-purpose cardiac catheter of claim 68 wherein said external thermal element comprises a heater coil wound about said necked-down portion.

71. The multi-lumen, multi-purpose cardiac catheter of claim 70, wherein said temperature measurement apparatus comprises a thermistor which is adjacent the distal end of said heater coil.

72. The multi-lumen, multi-purpose cardiac catheter of claim 70, wherein said heater coil comprises windings pitched at a center-to-center spacing sufficient to separate adjacent coils.

73. The multi-lumen, multi-purpose cardiac catheter of claim 70, wherein said heater coil is surrounded by a thin outer sheath to prevent said external thermal element from directly contacting the patient's blood.

74. The multi-lumen, multi-purpose cardiac catheter of claim 73, wherein said heater coil and said thin outer sheath generally approximate the diameter of said multi-lumen main body portion, thereby facilitating a smooth insertion of said multi-lumen main body portion into the body of the patient.

75. The multi-lumen, multi-purpose cardiac catheter of claim 67, wherein:

(a) at least one lumen of said multi-lumen main body portion is an injectate lumen and

(b) said injectate lumen is dedicated to proximal fluid infusion, thereby enabling injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said thermistor to provide values for use in calculating intermittent cardiac output values.

76. The multi-lumen, multi-purpose cardiac catheter of claim 67, wherein said external thermal element comprises a thin film member spirally wound about said multi-lumen main body portion near the distal end of said multi-lumen main body portion.

77. The multi-lumen, multi-purpose cardiac catheter of claim 67, wherein:

(a) said external thermal element comprises a heating filament printed on a substrate as a sandwich and

(b) said substrate is a thin material that is capable of being incorporated into a filament material that is flexible and has the ability to bond with an adhesive.

78. The multi-lumen, multi-purpose cardiac catheter of claim 67, wherein said external thermal element comprises a

layer of material with high thermal conductivity to help create a more uniform surface temperature.

79. A multi-lumen, multi-purpose cardiac catheter comprising:

- (a) a multi-lumen main body portion;
- (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and
- (c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and
- (v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber

optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

(h) an external thermal element is placed on said necked-down portion;

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

(k) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

80. A multi-lumen, multi-purpose cardiac catheter comprising:

(a) a multi-lumen main body portion;

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) a manifold providing an interface between said main body portion and said plurality of extension tubes, wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and
- (v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filament extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

(h) an external thermal element is placed on said necked-down portion;

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) at least one lumen of said multi-lumen main body portion comprises an injectate lumen;

(k) said injectate lumen is dedicated to proximal fluid infusion;

(l) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output;

(m) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation; and

(n) said injectate lumen enables injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said temperature measurement apparatus to provide values for use in calculating intermittent cardiac output values.--

B. 37 CFR 1.67(b)(2) is not relevant.

III. 37 CFR 1.67(C) IS NOT RELEVANT.

Signatures of the named inventors in accordance with 37 CFR 1.63(1) are provided below.

Date: 12 Oct 94

Michael D. Quinn
Michael D. Quinn

Date: 12 Oct 94

Mark L. Yelderman
Mark L. Yelderman

DOCKET NO.: IFLO-0002

PATENT

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I verily believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **A Thermodilution Catheter Having A Safe, Flexible Heating Element** the specification of which:

(xx) is attached hereto.

() was filed on _____ as Application Serial No. _____ and was amended on _____. (If applicable.)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 CFR § 1.56(a).

I hereby claim foreign priority benefits under 35 U.S.C. § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of any application on which priority is claimed:

Country	Number	Date Filed	Priority Claimed
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 CFR § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Philip S. Johnson and Michael P. Dunnam, Registration Nos. 27,200 and 32,611 of the firm of WOODCOCK WASHBURN KURTZ MACKIEWICZ & NORRIS, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania 19103, and

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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1-00	Full Name <u>D. Michael Quinn</u>	Inventor's Signature <i>Michael Quinn</i>	Date <u>1/20/91</u>
1	Residence <u>3121 Amesbury Drive, Plano, Texas 75093</u> Citizenship <u>USA</u> Post Office Address <u>Same as Above</u>		
2-00	Full Name <u>Mark L. Yelderman</u>	Inventor's Signature <i>Mark L Yelderman</i>	Date <u>1/21/91</u>
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4	Full Name	Inventor's Signature	Date
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